

Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Phone: (973) 596-4500
cchevalier@gibbonslaw.com

OF COUNSEL
David I. Berl
Christopher J. Mandernach
Seth R. Bowers
Michael Xun Liu
Kevin Hoagland-Hanson
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, NW
Washington, DC 20005
Phone: (202) 434-5000

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

PFIZER INC., WARNER-LAMBERT
COMPANY LLC, and PF PRISM IMB B.V.

Plaintiffs,

v.

C.A. No. _____

ZYDUS PHARMACEUTICALS (USA)
INC., ZYDUS WORLDWIDE DMCC and
CADILA HEALTHCARE, LTD.

Defendants.

COMPLAINT

Plaintiffs Pfizer Inc.; Warner-Lambert Company LLC; and PF PRISM IMB B.V. (collectively, “Pfizer”) file this Complaint for patent infringement against Zydus Pharmaceuticals (USA) Inc., Zydus Worldwide DMCC, and Cadila Healthcare, Ltd. (collectively, “Zydus”), and by their attorneys, hereby allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Zydus's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of IBRANCE® (palbociclib) capsules, 75 mg, 100 mg, and 125 mg, prior to the expiration of U.S. Patent No. 10,723,730 ("the '730 patent").

2. Zydus Worldwide DMCC notified Pfizer by letter dated September 11, 2020 ("Zydus's Notice Letter") that it had submitted to the FDA ANDA No. 213098 ("Zydus's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of generic Palbociclib capsules, 75 mg, 100 mg, and 125 mg ("Zydus's ANDA Product") prior to the expiration of the '730 patent. Zydus's Notice Letter purported to include an "Offer of Confidential Access" to Pfizer to Zydus's ANDA. In an exchange of correspondence, counsel for Zydus and counsel for Pfizer discussed the terms of Zydus's Offer of Confidential Access, though the parties were unable to agree on terms under which Pfizer could review the internal documents, data and/or samples relevant to infringement.

PARTIES

3. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is the holder of New Drug Application ("NDA") No. 207103 for the manufacture and sale of palbociclib capsules, 75 mg, 100 mg, and 125 mg, which has been approved by the FDA.

4. Warner-Lambert Company LLC is a limited liability company organized and existing under the laws of the State of Delaware, and having a place of business at 235 East 42nd Street, New York, New York 10017.

5. PF PRISM IMB B.V. is a private limited company (*besloten venootschap*) organized under the law of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands.

6. Upon information and belief, defendant Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

7. Upon information and belief, Zydus Worldwide DMCC is a company organized and existing under the laws of the United Arab Emirates with its principal place of business at Unit No 908, Armada 2, Plot No JLT PH2 P2A, Jumeirah Lakes, Dubai, United Arab Emirates. Upon information and belief, Zydus Worldwide DMCC is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

8. Upon information and belief, defendant Cadila Healthcare Ltd. is a company organized and existing under the laws of the Republic of India, with its principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad, Gujarat 380015, India. Upon information and belief, Cadila Healthcare Ltd. is in the business of, among other things,

manufacturing and selling generic versions of branded pharmaceutical products through various operating subsidiaries, including Zydus Pharmaceuticals (USA) Inc.

9. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. and Zydus Worldwide DMCC are wholly owned indirect subsidiaries of Cadila Healthcare Ltd. Zydus Pharmaceuticals (USA) Ind., Zydus Worldwide DMCC, and Cadila Healthcare Ltd. are collectively referred to herein as “Zydus.”

10. Upon information and belief, Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. acted in concert to prepare and submit Zydus’s ANDA to the FDA.

11. Upon information and belief, Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. know and intend that upon approval of Zydus’s ANDA, Cadila Healthcare Ltd. will manufacture Zydus’s ANDA Product and Zydus Pharmaceuticals (USA) Inc. and Zydus Worldwide DMCC will directly or indirectly market, sell, and distribute Zydus’s ANDA Product throughout the United States, including in New Jersey. Upon information and belief, Zydus Pharmaceuticals (USA) Inc., Cadila Healthcare Ltd., and Zydus Worldwide DMCC are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Zydus’s ANDA Product, and enter into agreements with each other that are nearer than arm’s length. Upon information and belief, Cadila Healthcare Ltd. and Zydus Pharmaceuticals (USA) Inc. participated in, assisted, and cooperated with Zydus Worldwide DMCC in that acts complained of herein.

12. Upon information and belief, following any FDA approval of Zydus’s ANDA, Zydus Pharmaceuticals (USA) Inc., Cadila Healthcare Ltd., and Zydus Worldwide DMCC will

act in concert to distribute and sell Zydus's ANDA Product throughout the United States, including within New Jersey.

JURISDICTION

13. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

14. Zydus Pharmaceuticals (USA) Inc. is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey, is qualified to do business in New Jersey, and has appointed a registered agent for service of process in New Jersey. It therefore has consented to general jurisdiction in New Jersey. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Pfizer's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

15. Zydus Worldwide DMCC is subject to personal jurisdiction in New Jersey because among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Zydus Worldwide DMCC develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Pfizer's

claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

16. Cadila Healthcare Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Cadila Healthcare Ltd., itself and through its wholly owned indirect subsidiaries Zydus Worldwide DMCC and Zydus Pharmaceuticals (USA) Inc., has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Cadila Healthcare Ltd., itself and through its wholly owned indirect subsidiaries Zydus Worldwide DMCC and Zydus Pharmaceuticals (USA) Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. In addition, Cadila Healthcare Ltd. is subject to personal jurisdiction in New Jersey because, upon information and belief, it controls Zydus Pharmaceuticals (USA) Inc. and Zydus Worldwide DMCC, and therefore the activities of Zydus Pharmaceuticals (USA) Inc. and Zydus Worldwide DMCC in this jurisdiction are attributed to Cadila Healthcare Ltd.

17. Upon information and belief, if Zydus's ANDA is approved, Zydus will directly or indirectly manufacture, market, sell, and/or distribute Zydus's ANDA Product within the United States, including in New Jersey, consistently with Zydus's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Zydus regularly does business in New Jersey, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in New Jersey. Upon information and belief, Zydus's

generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. Upon information and belief, Zydus's ANDA Product will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of Pfizer's patent in the event that Zydus's ANDA Product is approved before the patent expires.

18. Upon information and belief, Zydus derives substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and which are manufactured by Zydus and/or for which Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc. or Cadila Healthcare Ltd. is the named applicant on approved ANDAs. Upon information and belief, various products for which Zydus Pharmaceuticals (USA) Inc., Zydus Worldwide DMCC, or Cadila Healthcare Ltd. is the named applicant on approved ANDAs are available at retail pharmacies in New Jersey.

COUNT I – INFRINGEMENT OF THE '730 PATENT

19. Pfizer incorporates each of the preceding paragraphs 1–18 as if fully set forth herein.

20. The inventors of the '730 patent are Brian Patrick Chekal and Nathan D. Ide.

21. The '730 patent, entitled "Solid Forms of a Selective Cdk4/6 Inhibitor" (attached as Exhibit A), was duly and legally issued on July 28, 2020.

22. Pfizer is the owner and assignee of the '730 patent.

23. IBRANCE® is covered by one or more claims of the '730 patent, which has been listed in connection with IBRANCE® in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the Orange Book").

24. In Zydus's Notice Letter, Zydus notified Pfizer of the submission of Zydus's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the expiration of the '730 patent.

25. In Zydus's Notice Letter, Zydus also notified Pfizer that, as part of its ANDA, Zydus had filed a certification of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(B)(iv), with respect to the '730 patent. On information and belief, Zydus submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '730 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product.

26. On information and belief, Zydus's ANDA Product and the use of Zydus's ANDA Product are covered by one or more claims of the '730 patent, either literally or under the doctrine of equivalents.

27. As an example, claim 1 of the '730 patent recites:

A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a primary particle particle size distribution characterized by a D90 value of from about 30 μm to about 65 μm.

28. On information and belief, Zydus's ANDA Product infringes claim 1 of the '730 patent, literally or under the doctrine of equivalents.

29. Claim 7 of the '730 patent recites:

A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a

volume mean diameter characterized by a D[4,3] value of from about 15 μm to about 40 μm .

30. On information and belief, Zydus's ANDA Product infringes claim 7 of the '730 patent, literally or under the doctrine of equivalents.

31. Claim 15 of the '730 patent recites:

A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2 , 10.1 ± 0.2 and 11.5 ± 0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 μm to about 30 μm .

32. On information and belief, Zydus's ANDA Product infringes claim 15 of the '730 patent, literally or under the doctrine of equivalents.

33. Zydus's submission of Zydus's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product before the expiration of the '730 patent was an act of infringement of the '730 patent under 35 U.S.C. § 271(e)(2)(A).

34. On information and belief, Zydus will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product immediately and imminently upon approval of its ANDA.

35. On information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product would infringe one or more claims of the '730 patent, either literally or under the doctrine of equivalents.

36. On information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '730 patent.

37. On information and belief, Zydus plans and intends to, and will, actively induce infringement of the '730 patent when Zydus's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Zydus's activities will be done with knowledge of the '730 patent and specific intent to infringe that patent.

38. On information and belief, Zydus knows that Zydus's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '730 patent, that Zydus's ANDA Product is not a staple article or commodity of commerce, and that Zydus's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Zydus plans and intends to, and will, contribute to infringement of the '730 patent immediately and imminently upon approval of Zydus's ANDA.

39. Notwithstanding Zydus's knowledge of the claims of the '730 patent, Zydus has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Zydus's ANDA Product with its product labeling following FDA approval of Zydus's ANDA prior to the expiration of the '730 patent.

40. The foregoing actions by Zydus constitute and/or will constitute infringement of the '730 patent; active inducement of infringement of the '730 patent; and contribution to the infringement by others of the '730 patent.

41. On information and belief, Zydus has acted with full knowledge of the '730 patent and without a reasonable basis for believing that it would not be liable for infringement of the '730 patent; active inducement of the '730 patent; and/or contribution to the infringement by others of the '730 patent.

42. Pfizer will be substantially and irreparably harmed by infringement of the '730 patent.

43. Unless Zydus is enjoined from infringing the '730 patent, actively inducing infringement of the '730 patent, and contributing to the infringement by others of the '730 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT II – DECLARATORY JUDGEMENT OF INFRINGEMENT
OF THE '730 PATENT

44. Pfizer incorporates each of the preceding paragraphs 1–43 as if fully set forth herein.

45. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Pfizer on one hand and Zydus on the other regarding Zydus's infringement, active inducement of infringement, and contribution to the infringement by others of the '730 patent, and/or the validity of the '730 patent.

46. In Zydus's Notice Letter, Zydus notified Pfizer of the submission of Zydus's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the expiration of the '730 patent.

47. In Zydus's Notice Letter, Zydus also notified Pfizer that, as part of its ANDA, Zydus had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(B)(iv), with respect to the '730 patent. On information and belief, Zydus submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that that '730 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product.

48. On information and belief, Zydus's ANDA Product and the use of Zydus's ANDA Product are covered by one or more claims of the '730 patent.

49. As an example, claim 1 of the '730 patent recites:

A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2 , 10.1 ± 0.2 and 11.5 ± 0.2 and a primary particle size distribution characterized by a D90 value of from about $30\text{ }\mu\text{m}$ to about $65\text{ }\mu\text{m}$.

50. On information and belief, Zydus's ANDA Product infringes claim 1 of the '730 patent, literally or under the doctrine of equivalents.

51. Claim 7 of the '730 patent recites:

A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2 , 10.1 ± 0.2 and 11.5 ± 0.2 and a volume mean diameter characterized by a D[4,3] value of from about $15\text{ }\mu\text{m}$ to about $40\text{ }\mu\text{m}$.

52. On information and belief, Zydus's ANDA Product infringes claim 7 of the '730 patent, literally or under the doctrine of equivalents.

53. Claim 15 of the '730 patent recites:

A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2 , 10.1 ± 0.2 and 11.5 ± 0.2 and a volume mean diameter characterized by a D[4,3] value of from about $15\text{ }\mu\text{m}$ to about $30\text{ }\mu\text{m}$.

54. On information and belief, Zydus's ANDA Product infringes claim 15 of the '730 patent, literally or under the doctrine of equivalents.

55. On information and belief, Zydus will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product immediately and imminently upon approval of its ANDA.

56. On information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product would infringe one or more claims of the '730 patent.

57. On information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product in accordance with, and as directed by, its proposed labeling would infringe one or more claims of the '730 patent.

58. On information and belief, Zydus plans and intends to, and will, actively induce infringement of the '730 patent when Zydus's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Zydus's activities will be done with knowledge of the '730 patent and specific intent to infringe that patent.

59. On information and belief, Zydus knows that Zydus's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '730 patent, that Zydus's ANDA Product is not a staple article or commodity of commerce, and that Zydus's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Zydus plans and intends to, and will, contribute to infringement of the '730 patent immediately and imminently upon approval of Zydus's ANDA Product.

60. Notwithstanding Zydus's knowledge of the claims of the '730 patent, Zydus has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Zydus's ANDA Product with its product labeling following FDA approval of Zydus's ANDA prior to the expiration of the '730 patent.

61. The foregoing actions by Zydus constitute and/or will constitute infringement of the '730 patent; active inducement of infringement of the '730 patent; and contribution to the infringement by others of the '730 patent.

62. On information and belief, Zydus has acted with full knowledge of the '730 patent and without a reasonable basis for believing that it would not be liable for infringement of the '730 patent; active inducement of infringement of the '730 patent; and/or contribution to the infringement by others of the '730 patent.

63. Pfizer will be substantially and irreparably damaged by infringement of the '730 patent.

64. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of Zydus's ANDA Product with its proposed labeling, or any other Zydus drug product that is covered by or whose use is covered by the '730 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '730 patent, and that the claims of the '730 patent are not invalid.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

- (a) A judgment that the '730 patent has been infringed under 35 U.S.C. § 271(e)(2) by Zydus's submission to the FDA of Zydus's ANDA;
- (b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Zydus's ANDA Product, or any other drug product that infringes or the use of which infringes the '730 patent, be not earlier than the expiration date of the '730 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

- (c) A preliminary and permanent injunction enjoining Zydus, and all persons acting in concert with Zydus, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Zydus's ANDA Products, or any other drug product covered by or whose use is covered by the '730 patent, prior to the expiration of that patent, inclusive of any extension(s) and additional period(s) of exclusivity;
- (d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Zydus's ANDA Products, or any other drug product which is covered by or whose use is covered by the '730 patent, prior to the expiration of that patent, will infringe, induce the infringement of, and contribute to the infringement by others of, said patent;
- (e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;
- (f) Costs and expenses in this action; and
- (g) Such further and other relief as this Court may deem just and proper.

Dated: October 16, 2020

By: s/ Charles H. Chevalier
Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Phone: (973) 596-4500
cchevalier@gibbonslaw.com

OF COUNSEL:
David I. Berl
Christopher J. Mandernach
Seth R. Bowers
Michael Xun Liu
Kevin Hoagland-Hanson
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
(202) 434-5000

Attorneys for Plaintiffs